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Why Aren't Americans Getting the New COVID Vaccine? + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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Why Aren't Americans Getting the New COVID Vaccine?

U.S. News & World Report reported:

Americans who do not plan to get the latest COVID-19 vaccine mostly cite protection from prior infection and safety concerns as their primary reasons for not getting the shot, new survey data finds.

A Gallup survey conducted from late November to early December found that the majority of U.S. adults — 51% — don't plan on getting the updated shot. So far, 29% of respondents reported rolling up their sleeves for the vaccine, but an additional 20% said they plan to get the shot in the future. That means that close to half of Americans could get the latest shot if the numbers hold true in the real world.

Of those who don't plan to get the latest COVID-19 vaccine, 27% reported that their main reason for not getting the shot was having a prior coronavirus infection and believing they have antibodies.

The second most common reason was concern over the safety of the vaccine. While the COVID-19 vaccines have repeatedly proven to be safe, vaccine hesitancy fueled by the coronavirus pandemic remains a significant public health issue.

Deep Flaws in FDA Oversight of Medical Devices, and Patient Harm, Exposed in Lawsuits and Records

KFF Health News reported:

The pump, manufactured by device maker Medtronic, connected plastic tubing to an insulin reservoir, which Carlton "PeeWee" Gautney Jr. set to release doses of the vital hormone over the course of the day. Gautney, a motorcycle enthusiast, worked as a dispatcher with the police department in Opp, Alabama.

The 59-year-old died suddenly on May 17, 2020, because — his family believes — the pump malfunctioned and delivered a fatal overdose of insulin. The wrongful-death lawsuit alleges the pump was "defective and unreasonably dangerous." Medtronic has denied the pump caused Gautney's death and filed a court motion for summary judgment, which is pending.

The pump Gautney depended on was among more than 400,000 Medtronic devices recalled, starting in November 2019, after the company said in a recall notice that damage to a retainer ring on the pump could "lead to an over or under delivery of insulin," which could "be life-threatening or may result in death."

As the recall played out, federal regulators discovered that Medtronic had delayed acting — and warning patients of possible hazards with the pumps — despite amassing tens of thousands of complaints about the rings, government records show.

Merck Failed to Disclose Gardasil Autoimmune Issues Linked to HPV Vaccine, Lawsuit Alleges

AboutLawsuits.com reported:

Merck deceived federal regulators, hid disastrous side effects and manipulated medical reports to hide autoimmune issues caused by Gardasil HPV vaccines, according to allegations raised in a recently filed product liability lawsuit.

Mackenzie Gardett filed the complaint in the U.S. District Court for the Western District of North Carolina on December 12, indicating that she developed debilitating autoimmune disorders and life-altering side effects after receiving Gardasil injections when she was just 13.

Gardett and a growing number of other individuals who are now pursuing Gardasil lawsuits indicate that they have been left with permanent and life-changing autoimmune issues after receiving the HPV vaccination.

Talc Lawyer Rebuts J&J Bid to Disqualify Him, Denounces 'Smear Tactics'

Reuters reported:

A top plaintiffs' lawyer and his firm have urged a federal judge to reject Johnson & Johnson's (JNJ.N) bid to kick them off the mass tort litigation over the company's talc products, denying the company's claim that he formed an unethical alliance with a former J&J lawyer.

Andrew Birchfield and his firm, Beasley Allen, said in a brief filed in Trenton, New Jersey, federal court on Tuesday that J&J blamed them for defeating its two attempts at resolving the talc litigation in bankruptcy, which were dismissed by courts. Now, as the company has said it plans to pursue a third bankruptcy, it "seeks to have this court remove them as obstacles," the filing said.

"J&J lacks credibility in this challenge given the company's unhinged practice of bad faith bankruptcy filings, ad hominem attacks on opposing counsel, and unfounded efforts to disqualify any who oppose it," they wrote. "Practicing law is a profession, not a locker-room brawl."

The company earlier this month asked U.S. District Judge Michael Shipp to either disqualify Birchfield and Beasley Allen or remove them from the plaintiffs' steering committee, where they play a major role in coordinating plaintiffs' attorneys' work and shaping strategy.

Shipp is overseeing a consolidated mass tort litigation encompassing more than 50,000 lawsuits alleging that asbestos in the company's now-discontinued talc products causes cancer, most by women with ovarian cancer. The company has said its talc products are safe and do not contain asbestos.

The Year in Opioid Settlements: 5 Things You Need to Know

KFF Health News reported:

This year, about $1.5 billion has landed in state and local government coffers from court settlements made with more than a dozen companies that manufactured, sold, or distributed prescription painkillers and were sued for their role in fueling the opioid crisis.

That money has gone from an emerging funding stream for which people had lofty but uncertain aspirations to a coveted pool of billions of dollars being invested in real-time to address addiction.

Altogether, the companies are expected to pay more than $50 billion to state and local governments over nearly two decades.

Meanwhile, more than 100,000 Americans have died of drug overdoses annually in recent years, underscoring the urgent nature of the crisis.

As part of their settlements, manufacturers like Allergan and Johnson & Johnson agreed not to sell opioids for 10 years and curb marketing and promotion activities. Pharmaceutical distributors were required to step up efforts to identify suspicious orders from pharmacies, under the oversight of an independent third-party monitor. Retail pharmacy chains must conduct audits and site visits to their pharmacies, as well as share data with state agencies about problematic prescribers.

U.S. FDA Declines to Approve Merck's Chronic Cough Drug

Reuters reported:

The U.S. Food and Drug Administration (FDA) declined to approve Merck's (MRK.N) drug for chronic cough, the company said on Wednesday, marking the second rejection in less than two years.

The health regulator concluded the company's application for the drug, gefapixant, did not meet substantial evidence of effectiveness for treating refractory chronic cough and unexplained chronic cough. Currently, there are no approved treatments in the United States for coughing bouts that don't go away despite treatment of underlying conditions or have no identifiable cause.

The FDA's decision gives some breathing room to rival GSK's (GSK.L) chronic cough treatment camlipixant, which is in late-stage development with anticipated regulatory approval and launch in 2026.

The European Union and Japan have approved Merck's drug for the condition and it is sold under the brand name Lyfnua.

A Law to Help Neglected Diseases Is Giving Billion-Dollar Drugs Government Freebies

Bloomberg reported:

Vertex Pharmaceuticals Inc. has made over $20 billion in worldwide sales from a cystic fibrosis drug approved four years ago that can cost up to $300,000 a year.

With blockbuster sales like that, Vertex wouldn't appear to need government assistance. But thanks to an obscure program designed to incentivize companies to make drugs for uncommon or neglected diseases, the Food and Drug Administration also awarded Vertex a bonus certificate that it can either use to expedite a future drug approval or sell for around $100 million.

The program has exploded in recent years and vouchers are being granted for blockbuster drugs that would have been developed anyway, according to an analysis by Bloomberg News. The flood of vouchers has made them less lucrative for would-be sellers like small companies and nonprofits that need the cash to keep pursuing rare diseases.

Meanwhile, Big Pharma benefits. Eli Lilly & Co.'s popular diabetes drug Mounjaro came to market in 2022 — roughly four months faster than it normally would have — using a voucher. Lilly doesn't have to disclose information about the voucher it used, but it appears to be one the company purchased for $80 million in 2018. Mounjaro, which exploded in popularity due to its use in weight loss, has already surpassed $1 billion in quarterly sales.

Awarding a voucher to a drug with the potential to bring in more than $1 billion in sales "is laughable," says Harvard Medical School researcher Aaron Kesselheim. "It is not how the program was intended."

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7 days ago
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U.S. News & World Report reported: 'the COVID-19 vaccines have repeatedly proven to be safe'. Who do these lying scumbags think they are fooling? The data is in now on how useless they are and how incredibly dangerous to the victims they have been. When will these money grubbing serial liars be held responsible for the damage their misinformation has caused?
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